

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

SUPPLIER AUDIT REPORT

OF

MET ONE INSTRUMENTS

ROWLETT, TEXAS

**REPORT NUMBER OQA-SA-97-006
NOVEMBER 19, 1996**

Prepared by:

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Date: *12/18/96*

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Approved by:

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Date: *12/24/96*

**Donald G. Horton
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Enclosure

1.0 EXECUTIVE SUMMARY

The results of the supplier audit of Met One Instruments (MOI) conducted November 19, 1996, at their Rowlett, Texas, facility revealed unsatisfactory conditions resulting in the issuance of one Deficiency Report (DR) related to the Quality Assurance (QA) program for the Office of Civilian Radioactive Waste Management (OCRWM) activities. Not all of the required implementing procedures were developed for their scope of work and implementation was considered to be ineffective in some areas. The calibration services provided by MOI for this procurement are for use by the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O). MOI calibrates wind direction sensors and wind speed sensors for use in radiological monitoring activities.

The unsatisfactory conditions identified during the audit were discussed with the responsible MOI and M&O management. MOI management agreed to correct the unsatisfactory conditions. Corrective actions associated with DR YM-97-D-020 will be evaluated by the Office of Quality Assurance (OQA). Verification and closure will be performed by OQA. The unsatisfactory conditions are detailed in Section 5.0.

The results of the supplier audit warrant a recommendation for prohibiting MOI in providing the calibration services for the wind sensors until the noted deficiencies are corrected; however, responsibility for determination of acceptability for the use of this supplier and for the calibration services, will be determined by the M&O subject to verification by OQA.

2.0 SCOPE

The supplier audit was conducted to evaluate the adequacy, implementation and effectiveness of the MOI QA program. This was accomplished by determining if the MOI QA program meets the quality and technical requirements specified in the M&O Purchase Order Number A050606JM6E, the MOI Quality Control Manual, and the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 5, for the specific scope of work. The QA Program elements determined to be applicable are: Organization; QA Program; Procurement Document Control; Implementing Documents; Document Control; Control of Purchased Items and Services; Control of Measuring and Test Equipment; Corrective Action; QA Records and Audits.

3.0 AUDIT TEAM AND OBSERVERS

Daniel A. Klimas, Audit Team Leader, Office of Quality Assurance

4.0 PERSONNEL CONTACTED DURING THE AUDIT

Dennis Recla, Quality Control Manager, MOI
David Frith, Technician, MOI
Brad Parsley, Technician, MOI

5.0 SUMMARY OF AUDIT RESULTS

The MOI Quality Control (QC) Manual, revision date, March 1, 1995 and the implementing Quality Operating Procedures (QOPs) do not adequately address all the appropriate requirements of the OCRWM QARD for the intended scope of work. Not all implementing procedures have been developed that would describe the control for Implementing Documents; Document Control; Control of Purchased Items and Services; Corrective Action; QA Records and Audits. Additionally, there is no documentation available that provides evidence that employees have been trained to the MOI QA program or procedures. Purchase orders for calibration services do not contain adequate technical and quality requirements and supplier evaluations are not being performed for all suppliers. The review, approval, and distribution of implementing documents is not adequately described by procedure, or controlled. The MOI QC Manual is not being reviewed annually as required by the manual. The temperature and humidity recorder is past due for calibration. Measuring and test equipment calibration sheets are not being utilized as required by procedure. There are no documented controls or methods utilized to identify and segregate Measuring and Test Equipment that is out-of-calibration. Internal audits are not being performed as required by the QC Manual.

The details of the audit, along with the objective evidence reviewed and items corrected during the audit are contained within the audit checklist which is available from the OQA supplier audit files.

6.0 DEFICIENCIES/CORRECTED DURING THE AUDIT/RECOMMENDATIONS

The unsatisfactory conditions have been documented on DR YM-97-D-020 for corrective action and resolution. There were no conditions that were corrected during the audit and one recommendation provided to MOI's management for consideration and action as deemed appropriate. The recommendation is offered as a suggestion and is not required to be acknowledged unless otherwise stated.

DEFICIENCIES

1. MOI has not developed implementing procedures for the control of Implementing Documents; Document Control; Control of Purchased Items and Services; Corrective Action; QA Records and Audits.
2. There is no documented evidence that personnel performing quality related activities have been trained to the MOI quality program or procedures.

3. Purchase orders for suppliers of calibration services (i.e. Simcoe, Caltronics) do not contain adequate quality and technical requirements.
4. There is no documented evidence of supplier evaluations for all MOI suppliers.
5. There is no procedure requirements for the review, approval and control of implementing documents.
6. There is no method for the identification, distribution and control of implementing documents.
7. There is no evidence that the MOI QC Manual is reviewed annually as required by their manual.
8. The temperature and humidity recorder serial number 6529, is past due for calibration.
9. Measuring and test equipment utilized is not entered into the calibration system using the calibration sheets as required by their procedure.
10. There are no controls for identifying and segregating out-of-calibration equipment.
11. There is no evidence of internal audits being performed as required.

RECOMMENDATION

1. Some MOI organizational titles have recently changed. It is recommended that when new procedures are developed or revised and changes to the QC manual are made, that the organizational responsibilities and functional titles are consistent to assure actual responsibilities are clearly understood.